IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
AT NASHVILLE

MADISON A. WEST	)	
	)	
v.	)	**Case No. 3:24-cv-00279**
	)	
FARMAKEIO SUPERIOR COMPOUND PHARMACY *et al.*	)	

TO: Honorable Waverly D. Crenshaw, Jr., United States District Judge

REPORT AND RECOMENDATION

By Order entered March 15, 2024 (Docket Entry No. 7), this *pro se* civil action was referred to the Magistrate Judge for pretrial proceedings under 28 U.S.C. §§ 636(b)(1)(A) and (B), Rule 72(b) of the Federal Rules of Civil Procedure, and the Local Rules of Court.

Presently pending before the Court is the motion for summary judgment filed by Defendants Dan DeNeui, Dustin DeNeui, and Justin Graves. (Docket Entry No. 39.) Plaintiff opposes the motion. (Docket Entry Nos. 43, 44.) For the reasons set out below, the undersigned respectfully recommends that the motion be **GRANTED** and that this action be **DISMISSED**.

I. BACKGROUND

Madison West ("Plaintiff") is a resident of Nashville, Tennessee. On February 7, 2024, she filed this lawsuit in the Circuit Court for Davidson County. (Docket Entry No. 1-1.) Plaintiff seeks damages under the Tennessee Products Liability Act ("TPLA"), Tenn. Code Ann. §§ 29-28-105, *et seq*., for harm that she has suffered after taking a medication, Pyridoxine Hydrochloride/Semaglutide Acetate, that her medical care provider prescribed to her for weight loss. Named as defendants to her lawsuit are: (1) FarmaKeio Superior Compound Pharmacy, a.k.a.

FarmaKeio Compound Pharmacy, a business located in Texas ("FarmaKeio");[1] (2) Dan DeNeui; (3) Dustin DeNeui; and, (4) Justin Graves. The three individual defendants (hereinafter referred to collectively as "the Individual Defendants") are alleged to be the chief executive officer, chief operating officer, and pharmacy vice president, respectively, of FarmaKeio and are citizens and residents of Texas.

On March 8, 2024, the Individual Defendants timely removed the lawsuit to this Court on the basis of diversity jurisdiction. Notice of Removal (Docket Entry No. 1). Plaintiff thereafter filed an amended complaint (Docket Entry No. 10), to which the Individual Defendants filed an answer (Docket Entry No. 20). The docket does not reflect that Defendant FarmaKeio has responded to the complaint or amended complaint.

Pretrial activity in the case, including a period for discovery and the filing of discovery motions, occurred pursuant to a scheduling order. (Docket Entry No. 24.) Upon the Court's directive, settlement discussions occurred but a settlement agreement could not be reached. (Docket Entry Nos. 32, 36, 38.) All deadlines set out in the scheduling order have now expired, and there are no motions pending in the case other than the Individual Defendants' motion for summary judgment. A jury trial is demanded but has not been scheduled pending resolution of the motion for summary judgment.

II. PLAINTIFF'S ALLEGATIONS

In May 2023, Plaintiff was under the care of Chyrl Mosley ("Mosley"), a functional medical nurse practitioner in Franklin, Tennessee. Mosley prescribed for Plaintiff an injectable

[1] As set out *infra*, the Individual Defendants assert that the correct name of the business entity is North American Custom Laboratories, LLC d/b/a FarmaKeio Compounding.

medication for weight loss, Pyridoxine Hydrochloride/Semaglutide Acetate ("the Medication"). The prescription was filled by Farmakeio and was mailed to Mosley's practice where Plaintiff picked it up. Plaintiff was to inject the Medication into her body via subcutaneous injections on a weekly basis, and the prescription called for a gradually increasing dosage over a period of several weeks. Plaintiff alleges that the packaging for the Mediation contained no warning labels and listed no possible side effects from taking the medication.

Plaintiff took her first injection of the Medication as prescribed May 16, 2023, and took subsequent injections on May 24 and 31, 2023, and June 7, 14, and 23, 2023. Plaintiff alleges that she became increasingly sick each week and suffered side effects, which she reported to Mosley. Upon the recommendation of Mosley, Plaintiff was seen at the Vanderbilt Center for GI Disease in June 2023, where she underwent diagnostic testing and was diagnosed with severe gastroparesis, a condition that affects the proper functioning of the stomach muscles. Plaintiff alleges that this condition has required significant medical treatment, medical consults, and continuous diagnostic procedures, including but not limited to diagnostic testing and studies, lab work, and GI procedures under sedation. Plaintiff asserts that this has severely and negatively impaired all aspects of her life, both personally and professionally, causing her immense physical bodily impairment and pain, emotional distress and significant loss of quality of life. She alleges that the problems that she has experienced because of taking the Medication are ongoing and that the gastroparesis cannot be cured.

Plaintiff alleges that the adverse side effects of weight loss medications such as the Medication were known to Defendants but ignored by them and that they continue to distribute the Medication. She contends that Defendants were negligent in the design, manufacture, and

distribution of the Medication, and they failed to ensure that the Medication was safe for the intended use of weight loss. Plaintiff further contends that Defendants are liable under the Tennessee Products Liability Act because the Medication was in a defective condition or was unreasonably dangerous at the time it left their control.

III. MOTION FOR SUMMARY JUDGMENT

On January 31, 2025, the Individual Defendants timely filed the pending motion for summary judgment. The motion is supported by a memorandum of law (Docket Entry No. 40), a statement of undisputed material facts ("SUMF") (Docket Entry No. 41), and a small number of exhibits, including the affidavit of Dustin DeNeui (Docket Entry No. 40-2), an unsworn declaration from Plaintiff's husband (Docket Entry No 40-1), a copy of the electronic prescription order for the Medication (Docket Entry No. 40-3), a "Compounded Preparation Monograph" for the Medication, which is purportedly available through a QR Code (Docket Entry No. 40-4); and a printout purporting to show other prescriptions for the Medication that were ordered by Mosley and filled by FarmaKeio (Docket Entry No. 40-5).

The Individual Defendants argue that claims under the TPLA may only be pursued against manufacturers or sellers of a product, categories into which they do not fall since they are merely officers of FarmaKeio. They further argue that Plaintiff has no evidence the Medication was defective or unreasonably dangerous and that she cannot identify any specific defect about the Medication. Finally, the Individual Defendants maintain that Plaintiff cannot satisfy the causation element of her claim because she has no scientific, supported evidence that any defect or unreasonably dangerous condition in the Medication caused her injury and that her proof on causation is essentially based on speculation.

In response, Plaintiff provides a memorandum (Docket Entry No. 43), a response to the Individual Defendants SUMF (Docket Entry No,. 43-1), her own "affidavit of Authentication" (Docket Entry No. 43-2), and numerous exibits consisting of, among other things, excerpts from her medical records, copies of articles and reports from the United States Food and Drug Administration ("FDA"), copies of interrogatory responses from Defendants Justin Graves and Dustin DeNeui, and printouts from FarmaKeio's website. (Docket Entry Nos. 43-3 through 43-19, 44-1 through 44-17.)

After setting out a chronology of the medical problems that she experienced after taking the Medication, Plaintiff argues that her case should proceed to trial. She contends that it is undisputed that Defendants manufactured the Medication that she injected and further undisputed that she suffered gastroparesis and related medical complications after taking the Medication. She points to evidence of FDA warnings about using compounded medications, such as the one at issue, because of the risk associated with such medications and evidence that such medications are not FDA approved. Plaintiff further contends that the Individual Defendants provided her with only limited information in response to her discovery requests and that there is no merit to their argument that she does not have competent evidence to support her case. Asserting that she is not "required to be a pharmaceutical expert of a law scholar" (Docket Entry No. 43 at 10), Plaintiff argues that the evidence that she has provided is sufficient to support her case and to create genuine issues of material fact that must be resolved at trial.

IV. STANDARD OF REVIEW

A motion for summary judgment is reviewed under the standard that summary judgment is appropriate if "the movant shows that there is no genuine dispute as to any material fact and the

movant is entitled to judgment as a matter of law." Rule 56(a) of the Federal Rules of Civil Procedure. *See also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). "A genuine dispute of material fact exists 'if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.'" *Peffer v. Stephens*, 880 F.3d 256, 262 (6th Cir. 2018) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986).

The moving party has the burden of showing the absence of genuine factual disputes from which a reasonable jury could return a verdict for the non-moving party. *Anderson*, at 249-50. "The moving party may satisfy this burden by presenting affirmative evidence that negates an element of the non-moving party's claim or by demonstrating an absence of evidence to support the non-moving party's case." *Rodgers v. Banks*, 344 F.3d 587, 595 (6th Cir. 2003) (citation and quotations omitted). "In response, the nonmoving party must present 'significant probative evidence' that will reveal that there is more than 'some metaphysical doubt as to the material facts.'" *Miller v. Maddox*, 866 F.3d 386, 389 (6th Cir. 2017) (quoting *Moore v. Philip Morris Cos., Inc.*, 8 F.3d 335, 340 (6th Cir. 1993)). The party opposing the motion for summary judgment may not rely solely on the pleadings but must present evidence supporting the claims asserted by the party. *Banks v. Wolfe Cnty. Bd. of Educ.*, 330 F.3d 888, 892 (6th Cir. 2003). Moreover, conclusory allegations, speculation, and unsubstantiated assertions are not sufficient to defeat a well-supported motion for summary judgment. *Lujan v. National Wildlife Fed'n*, 497 U.S. 871, 888 (1990). In other words, to defeat summary judgment, the party opposing the motion must present affirmative evidence to support his or her position; a mere "scintilla of evidence" is insufficient. *Bell v. Ohio State Univ.*, 351 F.3d 240, 247 (6th Cir. 2003) (*quoting Anderson*, 477 U.S. at 252). In the end,

there must be evidence on which a trier of fact could reasonably find for the non-moving party. *Rodgers*, 344 F.3d at 595.

In reviewing a motion for summary judgment, the Court must view the evidence and all inferences drawn from underlying facts "in the light most favorable to the party opposing the motion." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp., Ltd.*, 475 U.S. 574, 587 (1986). The Court does not, however, weigh the evidence, judge the credibility of witnesses, or determine the truth of the matter. *Anderson*, 477 U.S. at 249.

V. ANALYSIS

The Court is not unsympathetic to the personal difficulties faced by Plaintiff over the last two years because of her continuing medical issues and the negative impact those issues have had on her life. The Court also acknowledges the daunting task faced by a *pro se* plaintiff who litigates a lawsuit without the assistance of counsel. This is especially so with respect to pursuing a products liability lawsuit, which can generally be said to be a challenging and complex type of case. *See e.g. In re Vioxx Prods. Liab. Litig.*, 574 F. Supp. 2d 606, 616 (E.D. La. 2008) ("all products liability cases pose significant challenges to plaintiffs' counsel"); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 176 F.R.D. 158, 185 (E.D. Pa. 1997) (noting that "[p]roducts liability actions can be quite complicated and the issues of actual and proximate cause elevate the complexity").

Nonetheless, while Plaintiff's *pro* se status affords her with some measure of leniency from the Court, this leniency has limits and *pro se* plaintiffs "are not automatically entitled to take every case to trial." *Pilgrim v. Littlefield*, 92 F.3d 413, 416 (6th Cir. 1996). The liberal treatment of *pro se* pleadings does not require lenient treatment of the substantive law, *Durante v. Fairlane Town Ctr.*, 201 F.App'x 338, 344 (6th Cir. 2006), and the liberal standards governing review of *pro se*

pleadings does not shield a *pro se* plaintiff's claims from more serious scrutiny as the case progresses to later stages, such as the summary judgment stage. *Johnson v. Stewart*, 2010 WL 8738105, at *3 (6th Cir. May 5, 2010); *Tucker v. Union of Needletrades, Indus., & Textile Employees*, 407 F.3d 784, 788-89 (6th Cir. 2005).

In the end, although Plaintiff has done an admirable job of presenting her case, the Court finds that the Individual Defendants present prevailing arguments for why they are entitled to summary judgment. Plaintiff fails to adequately rebut these arguments and show that the motion for summary judgment should be denied.

A. Plaintiff's Assertion About a Lack of Discovery

In her response to the motion for summary judgment, Plaintiff contends that she has been denied information that she requested through discovery, asserting:

> Defendants have provided no documentation in response to PLAINTIFF's INTERROGATORIES TO DEFENDANTS. Defendants willfully failed to provide relevant answers to questions and intentionally ignored requested documents. Three sets of Interrogatories for Defendants were sent to counsel with two responses returned: Dustin Deneui and Justin Graves. Dan DeNeui's Interrogatories were not responded to.

See Response at 7-8. She further asserts that:

> Federal Rule of Civil Procedure 26, allows Plaintiff to obtain key evidence from the Defendants such as internal documents, safety testing reports, or communications showing knowledge of product defects. Defendants have refused to provide Plaintiff with any such information

Id. at 10. Although not stated as such, Plaintiff's assertions essentially raise an argument that she cannot present facts essential to justify her opposition to the motion for summary judgment and thus relief under Federal Rule of Civil Procedure 56(d) is appropriate.

The problem with making such an argument at this point is that Plaintiff failed to raise the issue through a motion to compel during the time periods provided by the scheduling order for conducting discovery and for filing discovery motions. The deadline for completing discovery was November 2, 2024, and the deadline for filing discovery motions was December 2, 2024. (Docket Entry No. 24.) The scheduling order provided sufficient time for Plaintiff to engage in discovery, including filing discovery motions, but both deadlines passed without Plaintiff seeking an order compelling the Individual Defendants to provide additional or more complete discovery responses. Plaintiff's response to the motion for summary judgment is simply not the proper time to present a lack of discovery argument that should have been presented at an earlier time through a motion to compel. *See e.g. Schaffer by Schaffer v. A.O. Smith Harvestore Prods., Inc.*, 74 F.3d 722, 732 (6th Cir. 1996) (relief under Rule 56(f) [the predecessor to Rule 56(d)] was not warranted when the plaintiff did not bring the defendants' alleged numerous failures to comply with discovery requests to the attention of the court in a timely manner); *York v. Tennessee Crushed Stone Ass'n*, 684 F.2d 360, 363 (6th Cir. 1982) (relief under Rule 56(f) [the predecessor to Rule 56(d)] was not warranted when the plaintiff had ample opportunity for discovery); Ray v. Ogle, 2023 WL 3496948, at *4 (N.D. Ohio May 17, 2023) (Rule 56(d) motion was denied because the plaintiff had ample time for discovery and knew of the alleged shortcomings in the production from the defendants yet did not file a motion to compel despite sufficient time to file a motion); *Nethery v. Quality Care Invs., L.P.*, No. 3:17-CV-00537, 2019 WL 12023210, at *14 (M.D. Tenn. Feb. 11, 2019) (Newbern, J.) (a plaintiff's failure to file a motion to compel discovery was a factor in denying the plaintiff's Rule 56(f) to reopen discovery).

B. Tennessee Products Liability Act

The TPLA provides the statutory framework for bringing product liability claims. The TPLA applies to "all actions brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging or labeling of any product." Tenn. Code Ann. § 29-8-102(6). This "includes, but is not limited to, all actions based upon the following theories: strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent, or innocent; misrepresentation, concealment, or nondisclosure, whether negligent, or innocent; or under any other substantive legal theory in tort or contract whatsoever." *Id.* Given the scope of actions covered by the TPLA, it "supersede[s] common law claims for personal injuries stemming from alleged defects in products or failures to warn of the dangers associated with a product." *Merrell v. Summit Treestands, L.L.C.*, 680 F.Supp.3d 907, 915 (E.D. Tenn. 2023) (quoting *Coffman v. Armstrong Int'l, Inc.*, 615 S.W.3d 888, 895 (Tenn. 2021)).

Under the TPLA, a plaintiff must show the following in order to establish a *prima facie* case: (1) the product was defective and/or unreasonably dangerous; (2) the defect existed at the time the product left the manufacturer's control; and (3) the plaintiff's injury was proximately caused by the defective product. *Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 478 (6th Cir. 2008); *see Coffman*, 615 S.W.3d at 895-98); *King v. Danek Med., Inc.*, 37 S.W.3d 429, 435 (Tenn. Ct. App. 2000). These three elements apply in all TPLA cases regardless of the theories of liability that are asserted. *Hill v. Kia Motors, Inc.,* 2022 WL 557823 at *7 (6th Cir. Feb. 24, 2022). Under the TPLA, a "defective condition" is "a condition of a product that renders it unsafe for normal or

anticipatable handling and consumption." Tenn. Code Ann. § 29-28-102(2). A product is "unreasonably dangerous" if: (1) it is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics" or (2) "the product because of its dangerous condition would not be put on the market by a reasonably prudent manufacturer or seller, assuming that the manufacturer or seller knew of its dangerous condition." *Id.* § 29-28-102(8).

C. The Individual Defendants' Motion

The Individual Defendants first argue that they are entitled to summary judgment because Plaintiff cannot prove that they are manufacturers or sellers under the TPLA. The Court finds merit in this argument, including that it is determinative of the Individual Defendants' motion. Based upon the facts of this case, the three individual officers of FarmaKeio do not fall within the scope of defendants who may be held liable under the TPLA.

The TPLA provides for liability against a "manufacturer" or "seller" of a product. *Fox v. Amazon.com, Inc.*, 930 F.3d 415, 422 (6th Cir. 2019); *Strayhorn v. Wyeth Pharms, Inc.*, 737 F.3d 378, 403 (6th Cir. 2013); *Coffman*, 615 S.W.3d at 895-900. A "manufacturer" is defined as, "the designer, fabricator, producer, compounder, processor or assembler of any product or its component parts." Tenn. Code. Ann. § 29-28-102(4). A "seller" is defined as, "a retailer, wholesaler, or distributor, and means any individual or entity engaged in the business of selling a product, whether such sale is for resale, or for use or consumption. 'Seller' also includes a lessor or bailor engaged in the business of leasing or bailment of a product " Tenn. Code. Ann. § 29-28-102(7).

The three Individual Defendants are sued in this case because of their management roles in FarmaKeio. Clearly, as individuals, they did not make the Medication and are not therefore manufacturers under the TPLA. Although they hold management roles as individual officers of FarmaKeio, they are individually not retailers, wholesalers, or distributors of the Medication and thus are not sellers under the TPLA. In her response to the motion for summary judgment, Plaintiff fails to directly address this argument and fails to provide any evidence that would support a conclusion that the Individuals Defendants can be viewed as a manufacturer or seller under the TPLA.

The Court's independent research reveals no existing case law that would support a finding that individual officers of a business are manufacturers or sellers who can be face liability under the TPLA merely by virtue of their management roles. In the absence of controlling case law on the issue and a persuasive argument from Plaintiff, the Court declines to extend the definition of a manufacturer or seller under the TPLA to essentially cover any corporate or business officer who works for a business that manufactures or sells a product. While there may be unique factual scenarios in which a corporate or business officer may fall within the scope of the TLPA for the assessment of liability, Plaintiff has neither argued nor shown that this case presents such a scenario. The Individual Defendants are entitled to summary judgment in their favor for this reason alone.

Even if the Court were to find that the Individual Defendants fall within the definition of a manufacturer or seller under the TPLA, they are nonetheless entitled to summary judgment in their favor for a second reason. As the Individual Defendants argue, Plaintiff's proof on the causation element of her claim is insufficient to support her claim. Although Plaintiff provided various

excerpts from her medical records evidencing her medical issues, submitted her own affidavit of the medical issue that she has suffered, and attached to her response copies of articles/notices from the FDA and online websites about risks associated with use of compounded and non-FDA approved medicines for weight loss, she has not designated any healthcare provider as an expert or otherwise presented any type of expert testimony or proof on the issue of causation. As this Court recently stated in a TPLA case involving a medical device alleged to be defective and to have caused injuries to the plaintiff:

> Plaintiffs . . . are required to present expert testimony to establish causation in cases where the plaintiff has suffered a complex medical injury, *Tomazin v. Lincare, Inc.*, No. 3:13-CV-0875, 2015 WL 4545658, at *12 (M.D. Tenn. July 27, 2015) ("[U]nder Tennessee law, medical causation must be established by expert testimony."); *Thomas v. Aetna Life & Cas. Co.*, 812 S.W.2d 278, 283 (Tenn. 1991) ("Medical causation and permanency of an injury must be established in most cases by expert medical testimony."), or in products liability cases. *Pride v. BIC Corp.*, 218 F.3d 566, 580 (6th Cir. 2000) (citing *Fulton v. Pfizer Hosp. Prod. Group, Inc.*, 872 S.W.2d 908, 912 (Tenn. Ct. App. 1993); *Browder v. Pettigrew*, 541 S.W.2d 402, 404 (Tenn. 1976)) ("[U]nder Tennessee law, expert testimony is required to establish liability in cases alleging manufacturing and design defects."); *Jastrebski v. Smith & Nephew Richards, Inc.*, No. 02A01-9803-CV-00068, 1999 WL 144935, at *6 (Tenn. Ct. App. Mar. 18, 1999) (citing *Fulton*, 872 S.W.2d at 912) ("The product in dispute is a technically complex prescription medical device, and expert testimony is required to establish the causal connection between the alleged defect in the device and [p]laintiff's claimed injuries."); *but see Bradley v. Ameristep, Inc.*, 800 F.3d 205, 209 (6th Cir. 2015) (questioning the *Pride* court's interpretation of Tennessee law, and finding expert testimony unnecessary to prove causation in certain products liability actions).

Campbell v. DePuy Orthopaedics, Inc., No. 3:23-CV-00029, 2023 WL 2228978, at *3 (M.D. Tenn. Feb. 24, 2023). *See also Sigler*, 532 F.3d at 487 (disagreeing with the plaintiff's assertion in TPLA case that her injuries were "simple and routine" and thus Tennessee law does not require proof by expert testimony on the issue of causation). *Sanford v. L'Oreal USA S/D, Inc.*, No. 3:15-CV-1475, 2017 WL 2376922, at *2 (M.D. Tenn. June 1, 2017) (Trauger, J.) (granting summary

judgment to defendant in TPLA case in which the plaintiff had no expert testimony on the issue of causation). Given that Plaintiff's case involves a complex medical injury allegedly caused by the injection of the Medication, the lack of expert proof on the issue of causation is fatal to her claim and warrants the grant of summary judgment to the Individual Defendants.

D. Defendant FarmaKeio

Plaintiff's response to the motion for summary judgment does not differentiate between the Individual Defendants and Defendant FarmaKeio and simply refers to "Defendants," suggesting that she believes that FarmaKeio is both before the Court and is a moving party. However, the motion for summary judgment was filed by only the Individual Defendants. At the time of removal, the Individual Defendants noted that (1) Defendant FarmaKeio was incorrectly identified by Plaintiff in her complaint and that its correct name is North American Custom Laboratories, LLC d/b/a FarmaKeio Compounding and (2) North American Custom Laboratories, LLC d/b/a/ FarmaKeio Compounding had not been served with process. (Docket Entry No. 1 at 1-2.)

The Court specifically noted this deficiency in the March 15, 2024 order of referral. (Docket Entry No. 7 at 1.) The initial answer that was filed shortly after removal was filed only on behalf of the Individual Defendants, who also noted that "North American Custom Laboratories, LLC d/b/a FarmaKeio Compounding (incorrectly identified in the Complaint as Farmakeio Superior Compound Pharmacy) has not been served and is not an answering party." (Docket Entry No. 9.) Despite these notices, Plaintiff failed to either show proof of service of process upon FarmaKeio or take steps to have FarmaKeio properly served with process.

While Plaintiff's amended complaint did recognize the correct name of FarmaKeio, the amended complaint failed to actually list the correctly named business as a party. (Docket Entry No. 10 at 1-2.) Additionally, to the extent that Plaintiff intended by her amendment to add the correct defendant to the case, Plaintiff did not have a summons issued to North American Custom Laboratories, LLC d/b/a FarmaKeio Compounding to be served along with the amended complaint. While Plaintiff apparently contends that Defendant FarmaKeio is before the Court because the certificate of service for her amended complaint was sent to counsel for the Individual Defendants and to FarmaKeio at its business address in Texas (Docket Entry No. 35 at 1-2 and Docket Entry No. 10), service of a copy of the amended complaint is not sufficient to prefect service of process upon FarmaKeio given that there is no indication that it was ever properly served with process in the first instance or that it thereafter waived service of process.[2] *Leisure v. Ohio*, 12 F.App'x 320, 321 (6th Cir. 2001) ("The fact that a copy of the complaint was mailed to the defendants cannot substitute for proper service of process").

FarmaKeio is not before the Court because it does not appear to have ever been properly served with process in this case. Without proper service of process, a defendant is not before the Court and is not required to respond to the claims brought against it. *Harper v. ACS–Inc.*, 2010 WL 4366501 at *3 (E.D.Mich. Oct.28, 2010) (in the absence of proper service of process, defendant had no duty to respond); Rule 12(a)(1)(A). "Actual knowledge of a lawsuit does not

[2] The lack of service of process upon FarmaKeio and its absence from the case was also brought to Plaintiff's attention on several occasions subsequent to her amended complaint. *See e.g.* March 29, 2024, Order (Docket Entry No. 12) at 2; Answer to Amended Complaint (Docket Entry No. 20) at 1, n.1; Settlement Status Report (Docket Entry No. 32) at 1, n.1.

substitute for proper service under Fed. R. Civ. P. 4." *Bridgeport Music, Inc. v. Rhyme Syndicate Music*, 376 F.3d 615, 623 (6th Cir. 2004).

"Plaintiff bears the burden of showing the Defendant has been properly served with process." *Jones v. Stover Diagnostics Lab'ys, Inc.*, No. 3:19-CV-00740, 2023 WL 163138, at *4 (M.D. Tenn. Jan. 10, 2023) (Richardson, J.). Rule 4(m) of the Federal Rules of Civil Procedure requires that the defendant be served with process within 90 days of the date this action was filed and provides that, in the absence of a showing of good cause by the plaintiff for why service has not been timely made, the Court "must dismiss" the action without prejudice. Fed. R. Civ. P. 4(m). Given that the lack of service of process upon FarmaKeio was explicitly brought to Plaintiff's attention numerous times, yet she took no steps over the last year to cure this deficiency, the Court finds that the dismissal of FarmaKeio without prejudice under Rule 4(m) is warranted.

RECOMMENDATION

Based on the foregoing, it is respectfully **RECOMMENDED** that:

1) The motion for summary judgment filed by Defendants Dan DeNeui, Dustin DeNeui, and Justin Graves (Docket Entry No. 23) be **GRANTED** and that they be granted summary judgment in their favor and be **DISMISSED WITH PREJUDICE**.

2) Defendant North American Custom Laboratories, LLC d/b/a FarmaKeio Compounding be **DISMISSED WITHOUT PREJUDICE** pursuant to Fed. R. Civ. P. 4(m) for lack of service of process.

ANY OBJECTIONS to this Report and Recommendation must be filed with the Clerk of Court within fourteen (14) days of service of this Report and Recommendation and must state with particularity the specific portions of this Report and Recommendation to which objection is made.

See Rule 72(b)(2) of the Federal Rules of Civil Procedure and Local Rule 72.02(b)(1). A failure to file written objections within the specified time can be deemed a waiver of the right to appeal the District Court's Order regarding the Report and Recommendation. *See Thomas v. Arn*, 474 U.S. 140 (1985); *United States v. Walters*, 638 F.2d 947 (6th Cir. 1981). Any response to the objections must be filed within fourteen (14) days after service of such objections. *See* Federal Rule 72(b)(2) and Local Rule 72.02(b)(2).

Respectfully submitted,

BARBARA D. HOLMES
United States Magistrate Judge